

January 16, 2015

Via CDX

TSCA Confidential Business Information Center (7407M) EPA East - Room 6428 Attn: Section 8(e) U.S. Environmental Protection Agency 1201 Constitution Avenue, NW Washington, DC 20004-3302

Subject: Notice in Accordance with TSCA Section 8(e): Additional results of a Test Study in Male and Female Wistar Rats (Oral Administration – Gavage) with CASRN 63393-96-4

Dear Section 8(e) Coordinator:

BASF Corporation is submitting additional results of a Test Study in Male and Female Wistar Rats [Crl:WI(HAN)] with Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides, CASRN 63393-96-4 conducted by BASF SE, Ludwigshafen, Germany. The test substance is used as industrial chemical in solvent extraction process and as phase transfer catalyst.

This submission is supplementary to 8(e) notification, Case No. 8EHQ-14-19626

The test substance was administered once per day to groups of 4 male and 4 female Wistar rats via gavage for a maximum of 14 days. All animals were assessed by gross pathology and histopathological examinations of target organs.

The dose levels of the test substance were 0 and 50 mg/kg bw/d.

The following is a summary of the most relevant results:

50 mg/kg bw/d

- Two male and one female animal are found dead (each one at day 1, 2 and 3 of the study) and one female animal (at day 7 of the study) where sacrificed in a moribund state (showing i.e. hypothermia, gasping, piloerection)
- All male and female animals are showing salivation.
- All female an 3 of 4 male animals are showing respiration sounds
- Water- and Food consumption in the surviving animals was markedly decreased
- Body weight loss where seen in surviving animals
- Gross pathology revealed dilations and thickening of wall in fore- and glandular stomach as well as in duodenum, ileum, cecum, colon and rectum (incidence: from single animal up to all animals)



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- Results of the histopathological examinations:
 - Lungs, inflammation, pyogranulomatous, necrotic (3/4 males and 2/4 females)
 - Lungs, hyperplasia, broncho-alveolar (2/4 males and 1/4 females)
 - Nasal cavity, inflammation, neutrophilic, necrotic (3/4 males and 4/4 females)
 - Pharynx, inflammation, pyogranulomatous, necrotic (1/4 males)
 - Pharynx, infiltration, neutrophilic (2/4 males and 3/4 females)
 - Larynx, inflammation, pyogranulomatous, necrotic (2/4 males and 1/4 females)
 - Larynx, infiltration, submucosal (1/4 males and 1/4 females)
 - Larynx, hyperplasia multifocal (2/4 females)
 - Duodenum, thickening of mucosa (1/4 males and 2/4 females)
 - Forestomach, hyperplasia squamous (2/4 males and 2/4 females)
 - Glandular stomach, erosion, ulcer (1/4 males and 1/4 females)

BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note the technical contact and address below and direct all correspondence regarding this submission accordingly. If you have any questions, please call (248) 948-2051.

Sincerely,

Technical Contact: Alisa Boucher

BASF Corporation

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